**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| **IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION**<br><br>**This Document Relates to All Actions** | MDL No. 2875<br><br>Honorable Robert B. Kugler, District Court Judge |

**BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO COMPEL PRODUCTION OF TESTING AND OTHER MATERIALS IN THE POSSESSION OF CLASS EXPERT, DR. RON NAJAFI**

## I. INTRODUCTION

Plaintiffs' class expert, Dr. Ron Najafi, tested valsartan-containing drugs ("VCDs") for the potential presence of NDMA at the request of Valisure LLC in connection with a citizen petition submitted to FDA on June 13, 2019. The citizen petition showed the presence of NDMA in Novartis's product, which is the reference listed drug ("RLD") for generic VCDs. It also reflected testing performed on other manufacturers' VCDs, including Defendants in this MDL. Because these testing data—and any related methods, procedures, and communications—are relevant to the claims and defenses at issue in this litigation, Defendants request the Court to compel Plaintiffs to produce them.

## II. STANDARD

Federal Rule of Civil Procedure 26(b)(1) permits discovery of "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." The Rule is "construed liberally in favor of disclosure" as relevance encompasses "any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case." *Gov't Emps. Ins. Co. v. Trnovski*, No. 16-4662 (CCC), 2018 WL 5281424, at *2–3 (D.N.J. Oct. 23, 2018). "A party seeking to compel discovery bears the initial burden of showing that the information sought is relevant to the subject matter of the action. If that burden is met, the objecting party must specifically show how each discovery request is objectionable." *Emp'rs Ins. Co. of Wausau v. Daybreak Express, Inc.*, No. 16-cv-4269, 2017 WL 2443064, at *2 (D.N.J. June 5, 2017); *see also Williams v. Acxiom Corp.*, No. 15-cv-8464, 2017 WL 945017, at *3 (D.N.J. Mar. 10, 2017) (party resisting discovery has the burden of showing that the requests in question seek irrelevant information or are unduly burdensome or oppressive).

## III. BACKGROUND

Dr. Najafi has been disclosed by Plaintiffs as a class expert. He offers the opinion generic valsartan-containing medications that contained NDMA or NDEA at any level were not the "equivalent of" Novartis's RLDs, Diovan or Exforge. (ECF No. 1748-3, Najafi Rep. ¶ 34.) Dr. Najafi assumed for purposes of his report that the

Novartis products did not contain NDMA or NDEA at any level above zero. (Trischler Cert., Ex. A, Najafi Dep. Tr. 139:24–140:7.)

During the course of Dr. Najafi's deposition, Defendants learned Dr. Najafi and his laboratory, Emery Pharma, conducted testing in connection with a citizen petition submitted to FDA on June 13, 2019, by Valisure LLC. (*Id.* 141:17-142:2 [stating with "[o]ne hundred percent certainty" that Emery validated the testing performed by Valisure in connection with the citizen petition].) The Valisure citizen petition reflected testing for NDMA and an allegedly carcinogenic solvent, N,N-Dimethylformamide ("DMF"), performed on various manufacturers' valsartan-containing medications, including Novartis product. (*See* ECF No. 1984-1, Valisure Cit. Pet., at Appendix A.) Dr. Najafi confirmed that his lab "repeated Valisure's work" by testing "the same pills that [Valisure] tested" to confirm Valisure's results were "in the ballpark" of the levels detected by Emery. (Najafi Dep. Tr. 142:3-143:11.) Ultimately, Dr. Najafi was able to "corroborate" the nitrosamine data included in the Valisure citizen petition. (*Id.*)

The Valisure citizen petition showed detectable levels of NDMA in the majority of Novartis product tested, including a level of 17 nanograms in a 40 mg tablet. (ECF No. 1984-1, Valisure Cit. Pet., at Appendix A.) These data directly contradict the assumption underlying Dr. Najafi's opinion—i.e., that Novartis product did not contain nitrosamine impurities at any level above zero. Defendants'

notice of deposition had requested the production of any testing data and communications with third parties concerning nitrosamines in valsartan in Dr. Najafi's possession, custody, or control, but no documents were produced in response. (*See* ECF No. 1890, Najafi Not. of Dep.)

When confronted with the citizen petition at his deposition, Dr. Najafi backtracked from his prior, unequivocal testimony that his lab corroborated the nitrosamine levels reflected in the Valisure citizen petition. During re-direct by Plaintiffs' counsel, Dr. Najafi suggested that, because Emery Pharma is not identified in the citizen petition, his lab actually was not involved in any testing of product from Valisure. (Najafi Dep. Tr. 223:7-22.)

In the hope of settling the matter, Defendants followed up by letter on February 16, 2022, requesting production of documents reflecting any testing, methods, protocols, and procedures performed by Dr. Najafi or his lab on any valsartan-containing medications, as well as communications concerning the Valisure citizen petition. (*See* ECF No. 1984-2, Defs.' 2/16/22 Letter.)

Plaintiffs submitted a response on February 25, 2022. (*See* ECF No. 1984-3, Pls.' 2/25/22 Letter.) They took the position that Defendants' request for production of testing data was not "supported by the record," despite Dr. Najafi's unequivocal testimony that his lab had, in fact, conducted testing in support of the Valisure citizen petition. Plaintiffs suggested that further meet and confer would be helpful.

The parties met and conferred by telephone on March 8 and then again on March 11. During those discussions, Defendants directed Plaintiffs' counsel to the portions of Dr. Najafi's deposition where he explicitly stated that Emery Pharma had, in fact, tested valsartan-containing medications. Recognizing, however, the ambiguity created by subsequent testimony on re-direct by Plaintiffs' counsel, Defendants asked Plaintiffs to confirm one way or the other whether Dr. Najafi or his lab is in possession, custody, or control of any testing data or communications concerning the levels of nitrosamine impurities, if any, in valsartan API or finished-dose products. Plaintiffs committed to providing a response to this foundational question. Having not received any further substantive communications from Plaintiffs, Defendants followed up by email on March 22 and again on March 25. At that time, Plaintiffs suggested a response would be received by March 28. (*See* ECF No. 1984-4, 3/25/22 Email Chain.)

On March 29, Plaintiffs served their supplemental response.[1] Plaintiffs now acknowledge that Dr. Najafi did, indeed, conduct testing on valsartan provided by Valisure in connection with the citizen petition. Plaintiffs suggest that the samples from Valisure were "blinded," which Defendants interpret to mean Valisure did not expressly reveal the manufacturer of the drug to be tested by Emery Pharma.

[1] Plaintiffs have marked the letter Highly Confidential so, out of respect of that designation but without waiver of any potential challenges to that designation, Defendants will not attach it as an exhibit at this time.

Nonetheless, Plaintiffs surmise that none of the testing was performed on product manufactured by Novartis or the Defendants. The basis for this conclusion is nothing more than Dr. Najafi's comparison of the results of testing performed by his lab to the data set forth in the Valisure citizen petition. More specifically, because apparently none of the levels of NDMA and DMF measured by Dr. Najafi's lab was an exact match to the levels of NDMA and DMF reflected in the citizen petition, Dr. Najafi "advises" that he does not believe his testing was performed on Novartis's or any Defendant's product.

During the March 29 case management conference, Judge Vanaskie instructed the parties to continue meeting and conferring with respect to the dispute over Dr. Najafi's testing materials but, if no resolution could be reached, established a briefing schedule for Defendants' anticipated motion. (*See* ECF No. 1986, SMO 63.) The parties had a follow-up conference on April 6. At that time, Defendants maintained that they are entitled to all requested materials, irrespective of whether Dr. Najafi's testing results match those reported by Valisure. Moreover, Defendants noted that, due to potential margins of error and differences between methods, Dr. Najafi cannot reliably determine whether he tested Novartis's or Defendants' products based on nothing more than a comparison between Emery's results and Valisure's results. Plaintiffs were nonetheless unwilling to produce any documents. Instead, as a compromise, they offered to take another look at Dr. Najafi's records

to determine whether the levels of NDMA and DMF measured by Emery were within an unspecified margin of error as compared to the levels measured by Valisure in Novartis's or any Defendant's product. If not, Plaintiffs posited, Defendants would have reasonable assurance that none of the testing performed by Dr. Najafi is relevant to this litigation. Because Defendants do not believe Plaintiffs' compromise position is tenable and the parties have otherwise reached an impasse, Defendants now request the entry of an order compelling the production of all materials in Dr. Najafi's control relating to testing of VCDs for nitrosamines.

## IV. ARGUMENT

Defendants have requested production of the following materials from Plaintiffs:

1. The results of all testing performed by Emery Pharma and/or Valisure on any valsartan drug substance or drug product;
2. The standard operating procedures, protocols, methods (including validation) governing any such testing;
3. All reports and data generated related to any such testing;
4. The standard operating procedures, protocols, and policies related to the sourcing and chain of custody for all samples of valsartan drug substance or drug product received by Emery, including materials identifying the patient to whom the medication was prescribed, manufacturer, NDC, and batch/lot number;
5. All correspondence to, from, and among representatives of Emery Pharma and/or Valisure regarding any testing performed on valsartan or the citizen petition submitted to FDA on June 13, 2019; and
6. All invoices generated by Dr. Najafi and/or Emery Pharma related to this testing.

These data and related documents and communications are plainly relevant to class certification. First, the information bears on the two core assumptions underpinning Dr. Najafi's opinions—namely, that (i) all of the Defendants' generic valsartan contained nitrosamine impurities at some level above zero, and (ii) none of the Novartis product contained nitrosamines at any level. Even more broadly, testing demonstrating the presence or absence of nitrosamine impurities in the Defendants' valsartan goes to central questions at issue in this litigation, including the Rule 23 stage where Plaintiffs' class claims involve concepts of "Lifetime Cumulative Thresholds" and the alleged worthlessness of Defendants' medication.

There also is no doubt Dr. Najafi is in possession of materials responsive to Defendants' request. He said so himself, under oath.

> Q So the initial work that your lab was doing with respect to analysis of valsartan was done at the request of Valisure, not a lawyer?
> A [. . . .] That's correct. The initial work we did on valsartan was done at the request of Valisure.
> Q ***And you would have, consistent with your labs, stated desire to follow good laboratory practices, you would have all of the chain of custody sample, acquisition data, protocol data, test validation data and testing summaries from that Valisure work?***
> A ***Yes, I do.***
>
> ****
>
> Q What -- and then going back to your early valsartan work in the early part of 2018, you said that that was prompted by a contact from Valisure that asked you to do some testing. Can you tell me who or what information you received from Valisure that caused them to be interested in testing valsartan before the FDA was even aware of an issue?
> A So, you know, to be very frank to you, I don't know whether it was done before FDA official recall or after. I would have to check on that, but I

was contacted by the president of Valisure David Light and he wanted us to check the levels of NDMA in valsartan.

Q And you agreed to do that at his request?

A And he had data already. He also had GCMS data that showed high levels of NDMA genotoxic compound, and so I was very concerned because actually my mom was taking valsartan a few years ago, so I agreed to do the work. We might not have even charged them. I think we probably charged them, I don't know, but ***we ran the same pills that they had ran and we corroborated their data that indeed there were high levels of NDMA in valsartan, and we might have tested for NDEA as well***. I'm not sure.

Q What test method did you utilize during that initial testing?

A We used two or three official FDA methods that has been published. I think we used one of those methods.

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Q But what you did talk about and what you did explain to me was that Valisure brought the issue of the potential for nitrosamines in valsartan to your attention and sort of asked you to help with the testing and evaluation, right?

A ***One hundred percent.***

Q Okay. And so ***you had a chance to look at the testing that was done by Valisure early on on the valsartan and to independently validate it through the work of your own lab?***

A ***Yes, we did***.

Q ***So there is no question in your mind that the results of testing as documented by Valisure and its findings on nitrosamine contents in valsartan were accurate?***

A ***We repeated Valisure's work according to our own procedures and we, I think we – the result what we told Valisure was that the numbers they got was pretty much in the ballpark*** [. . . .] [W]e concurred with Valisure that they had correct nitrosamine numbers for their valsartan pills and they sent to us the same pills that they tested. I specifically warned Valisure to get it tested at a third-party lab. He called me, asked me for my advice. I said you want to get it at a third party lab to make sure. I think he was planning to do some press release or something, and that's what we did. And we told them yes, I think, and then he basically did something with that data.

Q. [ . . . . ] ***[D]id you have the opportunity and did in fact independently corroborate the Valisure data as it related to valsartan nitrosamine quantification?***

A ***That's correct. We corroborated their data.***

(Najafi Depo. Tr. 116:17–117:6, 119:20–121:1, 141:17–143:11 [emphases supplied].)

At deposition, Dr. Najafi confirmed he and his lab possess: (i) communications from Valisure requesting testing on VCDs; (ii) Valisure's testing data; (iii) testing data, chain of custody samples, acquisition data, protocol data, test validation data, and testing summaries from work performed by Emery; and (iv) communications from Emery to Valisure providing the results of Dr. Najafi's testing. This is anything but a fishing expedition. And even if Plaintiffs now try to walk back their expert's sworn testimony, the fact of the matter is the documents requested by Defendants are relevant impeachment evidence should Dr. Najafi try to change his story next time he is called to testify—whether at deposition or at trial.

Yet, Plaintiffs do not seem to dispute testing on Defendants' VCDs or Novartis's RLDs and related materials are relevant and discoverable. Instead, they maintain Dr. Najafi is not ***aware*** that he tested Defendants' or Novartis's products because the samples provided by Valisure supposedly were "blinded" and Emery's testing results ostensibly do not match those reported by Valisure for VCDs manufactured by Aurobindo or Novartis. Plaintiffs thus presume testing on any product other than Defendants' VCDs or Novartis's RLDs is irrelevant. Alternatively, Plaintiffs suggest the Novartis product tested by Valisure (and,

potentially, Emery) was a generic drug, not the RLD, or perhaps it was product from Europe.

None of Plaintiffs' positions hold up under scrutiny.

First of all, Defendants are at a loss for what Plaintiffs mean when they suggest the tablets received by Dr. Najafi from Valisure were "blinded." All that is required to identify the manufacturer of a drug is to conduct a visual inspection. Per 21 C.F.R. 206.10(a), "no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product."

The label for Novartis's Exforge,[2] for example, describes the appearances of the tablets by dosage.

- 5/160 mg Tablets - dark yellow, ovaloid shaped, film-coated tablet with beveled edge, debossed with "NVR" on one side and "ECE" on the other side
- 10/160 mg Tablets - light yellow, ovaloid shaped, film-coated tablet with beveled edge, debossed with "NVR" on one side and "UIC" on the other side
- 5/320 mg Tablets - very dark yellow, ovaloid shaped, film-coated tablet with beveled edge, debossed with "NVR" on one side and "CSF" on the other side
- 10/320 mg Tablets - dark yellow, ovaloid shaped, film-coated tablet with beveled edge, debossed with "NVR" on one side and "LUF" on the other side

[2] Trischler Cert., Ex. B, publicly available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021990s033lbl.pdf (last accessed Apr. 13, 2022).

Similarly, the label for Diovan[3] informs: "The 40 mg tablets are scored on one side and ovaloid with bevelled edges. 80 mg, 160 mg, and 320 mg tablets are unscored and almond-shaped with bevelled-edges." It further provides a table setting forth the visual characteristics and debossing by dosage of Diovan.

| Tablet | Color | Deboss | | NDC 0078-####-## | |
|---|---|---|---|---|---|
| | | Side 1 | Side 2 | Bottle of | |
| | | | | 30 | 90 |
| 40 mg | Yellow | NVR | DO | 0423-15 | – |
| 80 mg | Pale red | NVR | DV | – | 0358-34 |
| 160 mg | Grey-orange | NVR | DX | – | 0359-34 |
| 320 mg | Dark grey-violet | NVR | DXL | – | 0360-34 |

As such, it is not plausible for Dr. Najafi to suggest he is unable to identify the manufacturer(s) of the VCDs he tested.

But, on a more fundamental level, Plaintiffs' supposition that nothing in Dr. Najafi's possession is potentially relevant to this litigation ***other than*** testing performed on VCDs manufactured by Defendants and Novartis is flawed. Simply put, ***any*** testing for nitrosamines by Dr. Najafi or Valisure on VCDs is discoverable.

The very point of the Valisure citizen petition was to request FDA to recall from the U.S. market VCDs that Valisure deemed to be unsafe due to the presence of alleged carcinogens. Indeed, this entire MDL is founded upon Plaintiffs' belief

[3] Trischler Cert., Ex. C, publicly available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021283s053lbl.pdf (last accessed Apr. 13, 2022).

that trace levels of NDMA in VCDs can and did cause cancer in patients that used them. Plaintiffs' expert, Dr. Panigrahy, goes so far as to suggest "even one molecule of genotoxic chemicals may induce a mutation that may cause cancer." (ECF No. 1750-3, Panigrahy Rep., at 83.) Accepting that as true (as all of Plaintiffs' general-causation and class experts do), the potential presence of NDMA in any VCDs that might have been purchased or used by Plaintiffs—regardless of whether they were manufactured by Novartis or Defendants—is clearly relevant and discoverable on a whole host of issues, not the least of which are causation, alleged worthlessness, and predominance. It almost goes without saying, but certainly Defendants are entitled to materials relating to testing for nitrosamine impurities on any VCDs performed by or in the possession of Dr. Najafi.

To drive home this point, Defendants reviewed a small sampling of the pharmacy records produced in connection with this litigation. What those records show is that many named Plaintiffs have, in fact, purchased VCDs made by manufacturers ***other than Defendants*** who were identified in the Valisure citizen petition as having produced VCDs containing NDMA. By way of a few examples:

- Pharmacy records suggest the following personal-injury Plaintiffs used VCDs from Alembic, whose product Valisure found to contain as much as 180 ng of NDMA per tablet: David Little; Judy Lum; Crusita Murga; Gerald Nelson; Timothy Freeman; Nova Adams; and Darren Wilkerson.

- Pharmacy records suggest the following personal-injury Plaintiffs used VCDs from Macleods,[4] whose product Valisure found to contain as much as 59 ng of NDMA per tablet: Michael Jacobsen; Wanda Holcomb; James Childs; Richard Ramirez; Paulette Kennedy; James Stephens; Yolanda Bonmon; Terri Stine; and Joseph Gioia.

- Pharmacy records suggest the following personal-injury Plaintiffs used VCDs from Lupin, whose product Valisure found to contain as much as 13 ng of NDMA per tablet: John Kuntz; Donald Gray; Leisa Marie Brewer; Jennifer Johnson; Neal Matthews; Marlin Anderson; James Suits; Michael Svebek; Eugene Pate; Tivis Fields; Daniel Torghele; Margaret Ridley; and Lucille Mabie

It therefore cannot be seriously disputed that ***all testing*** performed by Dr. Najafi and Valisure for the potential presence of nitrosamines in VCDs is relevant, regardless of whether it came from Novartis, Defendants, or other manufacturers.

Plaintiffs suggestion during the meet-and-confer process that the "Novartis" product referenced in the Valisure citizen petition is not the RLD likewise falls flat. The citizen petition reflects testing performed on Novartis's 40 mg valsartan tablets (i.e., Diovan) and 320/12.5 mg valsartan/HCTZ tablets (i.e., Diovan HCT). (*See* ECF No. 1984-1, Valisure Cit. Pet., at Appendix A.) Notably, Novartis does not hold an ANDA for either generic valsartan or generic valsartan/HCTZ.[5] Nor does Novartis

[4] Macleods is, in fact, named in at least one Short Form Complaint in this MDL, *see, e.g.*, No. 1:20-cv-1352, though Plaintiffs maintained during the meet-and-confer process that Aurobindo was the only Defendant whose VCDs were tested by Valisure.

[5] *See* Trischler Cert., Ex. D, FDA Website (reflecting submitted ANDAs for generic valsartan but not showing Novartis); Ex. E, FDA Website (reflecting submitted ANDAs for generic valsartan/HCTZ but not showing Novartis); Ex. F,

manufacture an authorized generic form of Diovan, Exforge, or the other RLDs.[6] As such, the only reasonable inference to be drawn from the citizen petition is that Valisure did, indeed, find NDMA in Novartis's brand-name RLD.

During prior discussions, Plaintiffs' counsel has hinted that, perhaps, the Novartis product tested by Valisure was from the European market or maybe the Novartis product was made with API manufactured using something other than the "Novartis process," whatever that means. The first point is meritless. Valisure was requesting FDA to order a recall of certain VCDs from the U.S. market because the products supposedly were misbranded and adulterated under the FDCA. It would defy all logic for Valisure to make such a suggestion based on testing performed on product manufactured for a foreign market.

And the fact that Novartis may have been sourcing API from multiple vendors who may have utilized different manufacturing processes resulting in different impurity profiles is hardly surprising. That is because there is no such thing as a "Novartis process" that must always be utilized to manufacture API for Novartis's brand-name VCDs. Dr. Eric Sheinin, who spent decades at FDA, confirmed it is commonplace for NDA holders like Novartis to purchase ingredients from multiple

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Orange Book (reflecting approved drug products containing valsartan and showing Novartis only with respect to the RLDs).

[6] *See* Trischler Cert., Ex. G, FDA Listing of Authorized Generics, publicly available at https://www.fda.gov/media/77725/download (last accessed Apr. 13, 2022).

suppliers, each of whom might have unique processes, standards, and specifications. (ECF No. 2009-29, at Ex. 215, Sheinin Dep. Tr. 276:4–278:22.) FDA's records with respect to Diovan reinforce this point.[7] At bottom, irrespective of the source of API, Novartis's finished-dose product is the RLD and, if there was NDMA in the RLD, it contradicts one of the core assumptions underlying Dr. Najafi's opinions.

As excerpted above, Dr. Najafi testified unequivocally that he was able to confirm the data published in the citizen petition through independently validated testing methods performed on the exact same tablets as were analyzed by Valisure. As such, irrespective of whether Emery corroborated Valisure's results with respect to Novartis product in particular, the fact that Dr. Najafi's lab corroborated at least some of Valisure's data is clearly germane to the claims and defenses at issue. This is particularly so in light of the fact that Dr. Najafi apparently is willing to accept at face value, without any validation by his own lab, the results of Health Canada's testing, finding no NDMA or NDEA in Diovan. (Najafi Dep. Tr. 222:19–21.) Certainly, then, documents and communications concerning Valisure's data, which have been corroborated by Dr. Najafi, must be produced.

[7] For example, FDA records show, in July 2021, Novartis amended its NDA to add a new API supplier for Diovan. The use of a new vendor required the adoption of additional specifications and tests, which is inconsistent with Plaintiffs' notion there is a singular process for the manufacture of all API incorporated into Novartis's RLDs. *See* Trischler Cert., Ex. H, FDA Letter, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/021283Orig1s059ltr.pdf (last accessed Apr. 13, 2022).

## CONCLUSION

WHEREFORE, Defendants respectfully request the Court to enter an order compelling the production of any and all materials within Dr. Najafi's possession, custody, or control relating to testing performed on VCDs.

Dated: April 13, 2022

Respectfully Submitted:

By: */s/ Clem C. Trischler*
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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on April 13, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

*/s/ Clem C. Trischler*
Clem C. Trischler